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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/606,909 | 06/29/2000 | Ronald J. Pettis | P-4901 | 7814 |
| 20583 | 7590 | 06/15/2004 | EXAMINER | |
| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | | HAYES, MICHAEL J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/606,909 | PETTIS ET AL. | |
| | Examiner | Art Unit | |
| | Michael J Hayes | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7, 10-24 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7, 10-16 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of claim 29 in the reply filed on 3/19/2004 is acknowledged. Though Applicant stated that the restriction should be withdrawn, Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement. Therefore, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 17-24 are listed as withdrawn.

Claims 2-7, 10-16, and 29 remain pending and are treated on the merits below.

Claim Status Clarification

Applicant is requested to clarify the status of claims 17-24. In the paper received 3/19/04 these claims were listed as withdrawn, but in paper received 10/08/02 these claims were not mentioned as pending. It appears that the 10/08/02 paper considered these claims as cancelled. Due to this inconsistency Applicant is requested to clarify the status of these claims. The examiner is currently treating these claims as withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for higher plasma concentration by intradermal over subcutaneous injection for some times, does not reasonably provide enablement for higher plasma concentration by intradermal injection over subcutaneous injection for all times. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant has not shown how to achieve higher plasma concentration by intradermal injection versus subcutaneous injection over all time periods shown in the disclosed data. Applicant's data (figs. 1-5) does not show a consistently higher concentration for intradermal injection, but rather a concentration that is sometimes higher and sometimes lower than the concentration achieved by subcutaneous injection.

Claims 2-7, 10-16, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: those steps disclosed by Applicant to be essential to the method, which include, providing a particular needle length and exposed height to achieve the claimed delivery, applying a constant pressure directly on the liquid interface, and controlling delivery rates and volumes to achieve the claimed invention. Applicant has stated in the specification and submitted arguments that the steps listed above are essential to the practice of the claimed method. See specification (pg. 2, lines 13-16, pg. 3, lines 1-4, pg. 3, lines 13-15, pg. 4, line 29 - pg. 6, line 6). See paper submitted 3/19/2004 pgs. 5-8. Applicant's delivery rates, delivery volumes, delivery pressures, needle lengths, and needle exposed height should be

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recited in the independent claim as they are disclosed as essential limitations required to practice the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 5-7, 10-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by GROSS et al. (US Patent No. 5,848,991). Gross discloses a method of delivering insulin intradermally (3:40-41) using a single needle with an outlet at a depth of 250 μ m - 2mm in a controlled manner based on needle diameter (4:10-35). The plasma profile is inherently similar to, but higher as compared to subcutaneous injection. It is reasoned that the needle length is the essential limitation required to inherently achieve the claimed method because this is the only needle structural limitation recited by the Applicant in the currently pending claims.

Claims 29, 4, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by GANDERTON et al. (US Patent No. 3,814,097). Ganderton discloses injecting a substance through multiple needles with a zero exposed height (2:37-55) with an outlet at 1000 μ m (2:55-60). See fig. 1. The plasma profile is inherently similar to, but higher as compared to subcutaneous injection. It is reasoned that the needle length is the essential limitation required to

inherently achieve the claimed method because this is the only needle structural limitation recited by the Applicant in the currently pending claims.

Claim 29, 2, 3, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by AUTRET et al. (Therapie 1991; 46:5-8). Autret discloses intradermal injection of a hormone that results in a pharmacokinetic profile similar to subcutaneous delivery, but with a higher plasma level. See fig. 1.

Response to Arguments

Applicant's arguments are moot in view of the new grounds of rejection. Applicant has made comments with respect to the Gross reference in a previous paper (received 7/14/2003), and the examiner will comment below on some of Applicant's previous arguments as appropriate.

Applicant argued that Gross does not deliver to the intradermal compartment because the term "intradermal delivery" does not mean delivery to the intradermal compartment where it is absorbed. The examiner does not agree and points to Applicant's claim limitation of delivering into an intradermal compartment and Gross's disclosure of delivering a drug to the interior of the dermis (3:38-44) as the same delivery.

Applicant argues that Gross cannot provide inherent anticipation because Gross's disclosed example could not be delivered to the intradermal compartment. The examiner points out that Gross is not held only to disclosed embodiments and Gross discloses more than only delivery to intradermal compartment (3:38-40). Gross does not disclose that his examples are delivery to the intradermal compartment (10:31-62).

Applicant argues that Gross did not measure the pharmacokinetic profile or report any insulin levels. The examiner points out that these steps are not recited in Applicant's claimed method.

Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
11 June 2004


MICHAEL J. HAYES
PRIMARY EXAMINER